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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,060	01/03/2002	Frank Frantzen	09100.021	1169

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Karen Lee Orzechowski
Liniak Berenato Longacre & White
Suite 240
6550 Rock Spring Drive
Bethesda, MA 20817

EXAMINER

DAVIS, DEBORAH A 6

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,060

Applicant(s)

FRANTZEN, FRANK

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 4-11 and 16-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed June 25, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Currently application EP 0 483 512 and JP 043293570 has not been considered because there is not translation and its relevance to the present application is not clear.

Claim Objections

2. Claims 4-11 and 16-20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or; neither can said claims depend from any other multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 is vague and indefinite because it is not clear how the complex is being formed. When the sample is contacted with the SAH and the SAH hydrolase moiety it is unclear how the reactants interact with the sample. Does the hydrolase bind the homocysteine in the sample or does it bind the SAH moiety? The steps in the assay are not clear. Also, the limitation "the hapten" recited in line 5 is vague because it is unclear whether the hapten refers to the SAH or the SAH hydrolase moiety.

Claim 1, recite the term "comprising", in line 4 is vague because it is not clear as to what this term refer too. Line 4, recite the term "hapten moieties" is vague because it is not clear how this term relate to "polyhapten", the term recited in line 4. Lines 5-6, recite the term "as hapten moiety the hapten", please explain what this is. Line 8, recite the term "if desired" is not a positive recitation. Line 9, recite the term "a further enzyme", please point out the first enzyme. In line 15, recite the term "said enzymes" what enzyme does this phrase refer too?

7. Claim 2, recite the term "one of said reagents" is vague because it is unclear which reagent contain what element.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cockbain et al (WO93/15220).

Cockbain et al teaches a method for assaying homocystein in a sample, such as blood, plasma or urine which comprises the steps of contacting said sample with a homocysteine converting enzyme (SAH hydrolase) and an analyte selected from a homocysteine co-substrate and conversion products (page 3, paragraph 6). The assay of the invention is conveniently uses enzymatic or immunological techniques to detect the analyte in question (page 4, paragraph 5). However, methods based on enzymatic reaction, or reaction with monoclonal or polyclonal antibodies is particularly preferred which may be detected photometrically (page 8, paragraph 2). In a preferred immunological technique, the analyte is assessed using a competitive binding assay to an antibody by the analyte (SAH) and a further hapten or polyhapten or labeled analogue of the analyte. To obtain an estimate of the total homocysteine present in the sample, it may be treated with a reducing agent to liberate free homocysteine (page 7, paragraph 4 and page 8, paragraph 1). Other immunological methods for the analyte (SAH) can include a sandwich assay that employs a second antibody can be reacted

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further to form detectable products, as recited in claims 2 (page 9, paragraph 1).

Beside the use of spectrometric or other photometric techniques, precipitation inhibition or particle agglutination inhibition techniques can be used, which rely on the use of antibody/hapten combinations which on conjugation lead to precipitation or particle aggregation which can be detected by turbidimetric or nephelometric measurement, as recited in claim 3. Where the antibody/hapten complex formation is inhibited by the analyte, e.g. SAH, the SAH content may be assessed from the reduction in precipitation/aggregation (page 14, paragraph 2). Claims 12-15 are anticipated by teaching various kit configurations structured for clinical assay use that include reagents such as reducing agents (DTT) with a low buffer and a separate solution of SAH-hydrolase at a neutral PH and preferable buffered. In another embodiment the kit comprises adenosine; s-adenosyl-homocysteine (SAH); anti-S-adenosyl-homocysteine antibody, means for photometrically assessing agglutination or precipitation of antibody: polyhapten complexes and other reagents i.e., polymers (carrier proteins) (pages 23-25).

Conclusion

10. No claims were allowed.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

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A. Erling Sundrehagen (EP 0 726 322 A1) teaches a method for assaying a homocysteine in a sample.

B. Erling Sundrehagen (USP#5,827,645) teaches a method for assaying homocysteine in a sample.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.



Deborah A. Davis
CM1, 7D16
March 24, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

03/24/03